



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 19 1985

EXPEDITE

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Special Review Action Code 870 - Maneb Data Call-In [RCB No. 7]. Evaluation of Product Chemistry Data for Technical Maneb Produced by BASF Wyandotte (EPA Registration No. 7969-11) - Accession Number 259465.

FROM: Michael P. Firestone, Ph.D., Chemist
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Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Michael P. Firestone
[Signature]

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Susan Lewis
Data Call-In Program
Registration Division (TS-767C)

and

Henry Jacoby, Product Manager No. 21
Registration Division (TS-769)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Note: This EDBC data package has been submitted in connection with the NRDC lawsuit. All EDBC reviews are being expedited per the request of Mr. Douglas D. Campt, Registration Division Director (see D. Campt memo of June 28, 1985 to J. Melone, HED Director).

BASF Wyandotte Corporation has submitted product chemistry data for Maneb Technical Grade (EPA Registration No. 7969-11) in response to a Data Call-In dated October 19, 1984. The registrant notes that physical and chemical properties of maneb are not included in the current submission (dated September 10, 1985) since they were previously submitted by the Maneb Task Force (see E. G. Pazianos letter of August 29, 1985 to G. W. Werdig of EPA).

The data will be presented below in the format of the Product Chemistry Guidelines, Subdivision D of 40 CFR 158, along with RCB's comments/conclusions regarding the adequacy of the data.

Series 61: Product Identity and Composition

\$61-1. Product Identity and Disclosure of Ingredients

Submission: Confidential Statement of Formula (CSF) for Maneb Technical Grade (EPA Registration No. 7969-11) dated September 10, 1985 (see Confidential Appendix of this review).

RCB's Comments/Conclusions: The Section 61-1 data requirements for Maneb Technical Grade (EPA Registration No. 7969-11) have not been adequately satisfied [REDACTED] intentionally added inerts (see Confidential Appendix Part B) are not listed in the CSF.

\$61-2. Description of Beginning Materials and Manufacturing Process

Submission: A very brief description and flow chart of the manufacturing process and specifications of starting materials.

RCB's Comments/Conclusions: With regard to the starting materials, the registrant will need to submit the names and addresses of all suppliers and their technical specification sheets as specified in the Guidelines. Concerning the manufacturing process, a detailed and complete description must be submitted as specified in The Guidelines (\$61-2(b)(1-9)).

\$61-3. Discussion of the Formation of Impurities

Submission: A brief discussion concerning the formation of one concerned impurity.

RCB's Comments/Conclusions: The registrant should discuss whether any impurities other than those listed in the CSF could possibly be formed during the manufacturing process, including those formed by contaminants in the various starting materials, and discuss the results of sensitive methods of determination for these compounds such as HPLC or GC-MS as required in the next section.

Series 62: Analysis and Certification of Product Ingredients

\$62-1. Preliminary Analysis of Product Samples

Submission: The results of five batch analyses of Maneb technical have been submitted (see Confidential Appendix of this review).

RCB's Comments/Conclusions: The data requirements for Section 62-1 are not satisfied. The registrant should carry out more extensive studies to characterize all impurities in technical maneb present at $\geq 0.1\%$.

\$62-2. Certification of Ingredient Limits

Submission: The CSF for EPA Registration No. 7969-11 includes certified limits.

RCB's Comments/Conclusions: Two components identified in the batch analyses are not specifically included in the CSF. The registrant should list these components in the appropriate spaces on the CSF for EPA Registration No. 7969-11.

\$62-3. Analytical Methods to Verify Certified Limits

Submission: Analytical methods to determine the ai and various impurities and inerts (see Confidential Appendix of this review).

RCB's Comments/Conclusions: The registrant must develop analytical methods (such as HPLC, etc.) to determine compounds other than maneb present at $\geq 0.1\%$ by weight which could mistakenly be determined as maneb by Method No. VN-1428. In addition, the registrant will need to discuss the precision and accuracy of all analytical methods as well as submit validation data.

Series 63: Physical and Chemical Characteristics

Submission: With regard to data concerning the physical and chemical properties of maneb, the registrant states that this package was included in a letter from E. G. Pazianos of the Maneb Task Force dated August 29, 1985 to G. W. Werdig of EPA.

According to the August 29, 1985 letter, the Maneb Task Force consists of the following companies:

BASF Wyandotte Corporation (EPA Company No. 7969-)
 Griffin Corporation (EPA Company No. 1812-)
 Pennwalt Corporation (EPA Company No. 4581-)
 Rohm and Haas Company (EPA Company No. 707-)

The August 29, 1985 letter also refers to Series 63 data included with a August 19, 1985 letter from E. G. Pazianos of the Maneb Task Force to G. W. Werdig of EPA.

RCB's Comments/Conclusions: The registrant will need to generate Series 63 physical and chemical properties data on the technical chemical (whether or not registered) and all manufacturing-use products and end-use products produced by an integrated formulation system currently registered. The physical and chemical properties are expected to vary from product to product. If the data supplied by the Maneb Task Force were generated on any BASF Wyandotte products, these will be considered applicable only for the products upon which they were generated.

Finally, Series 63 data should be supported by raw data and descriptions of how the data were generated.

Recommendations

The registrant should be informed of the above deficiencies in the maneb product chemistry data. Complete product chemistry data requirements are cited in the 40 CFR 158, Subdivision D Guidelines. Separate Series 63 data should be submitted for each maneb manufacturing-use product (MUP), end-use product (EUP) produced by an integrated formulation system, and the technical chemical (whether registered or not).

The registrant should be informed that upon completion of RCB's review of all relevant metabolism and residue data requested so that the metabolism/degradation products of toxicological concern are identified, additional product chemistry information may be requested.

Attachment 1: Confidential Appendix - 3 pages

cc(with Attachment 1): SLewis(RD), PM#21, TOX, MPFirestone,

EDBC S.F., R.F., PMSD/ISB

cc(without Attachment 1): Circu

RDI:JHOnley-11/5/85:RDSchmitt-11/6/85

TS-769:RCB:MPFirestone:Rm800b:557-7484:CM#2

typed by Kendrick Contractor-11/13/85: edited by:wh:11/15/85

Maneb residue chemistry review

Page _____ is not included in this copy.

Pages 5 through 7 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
 - ☐ Identity of product impurities
 - ☒ Description of the product manufacturing process
 - ☒ Description of product quality control procedures
 - ☐ Identity of the source of product ingredients
 - ☐ Sales or other commercial/financial information
 - ☐ A draft product label
 - ☐ The product confidential statement of formula
 - ☐ Information about a pending registration action
 - ☐ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
 - ☐ The document is not responsive to the request
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
